Spring 6-5-2016

Less Drugs but Lots of Drug News to Open 2016

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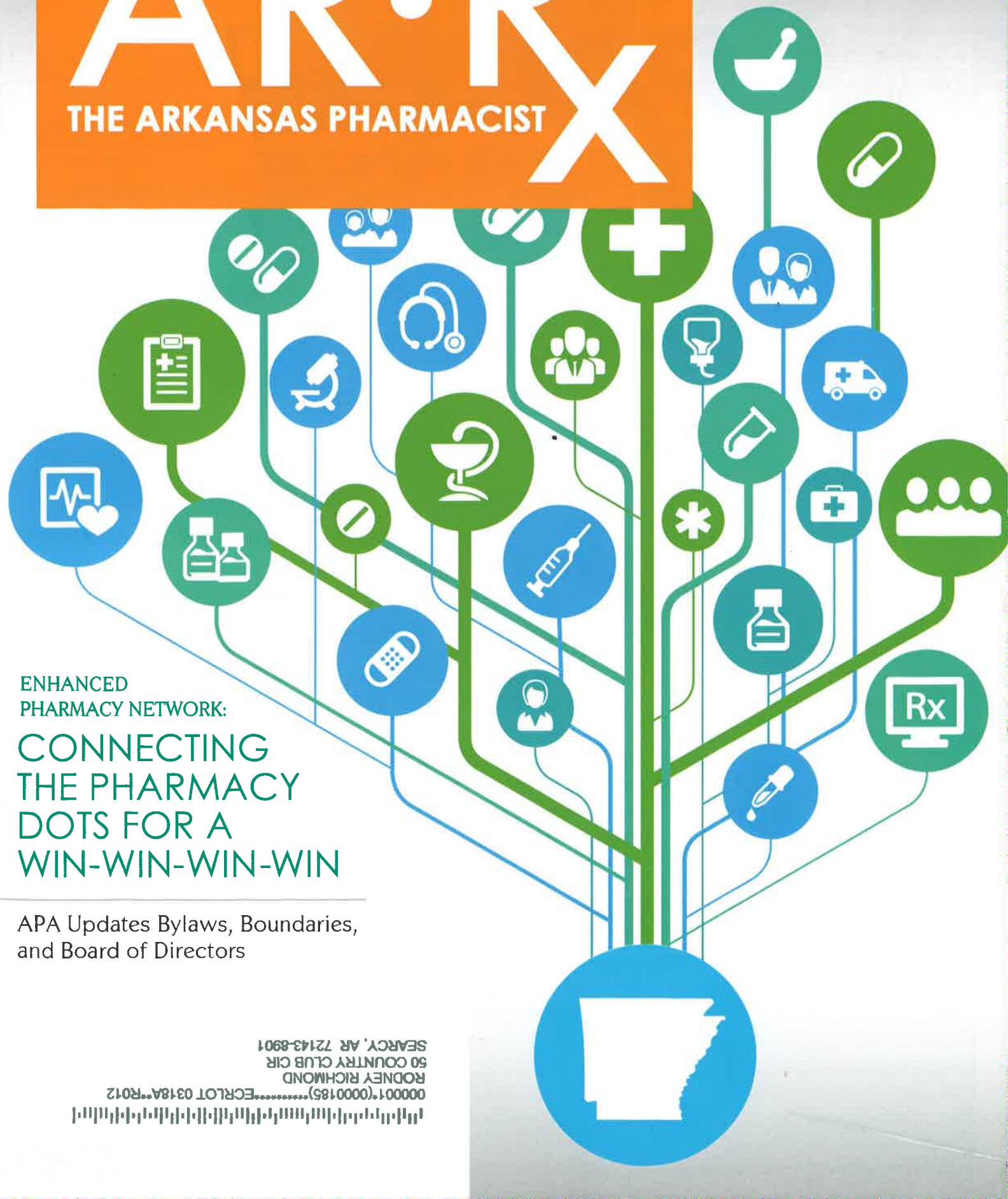
SPRING 2016

Award Winning Quarterly Publication of the Arkansas Pharmacists Association

AR·Rx

THE ARKANSAS PHARMACIST



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New Drugs

By Rodney G. Richmond, RPh, MS, CGP, FASCP

Less Drugs but Lots of Drug News to Open 2016

This column, presented by the Harding University College of Pharmacy, aims to briefly highlight information on new molecular or biological entities, new indications, or significant new dosage forms recently approved by the FDA

The FDA finished out 2015 on a high-note with the approval of 26 new molecular or biological entities and a bevy of significant new drug formulations.

Drugs In the News: Although things are slow out of the gate so far this year, 2015 was a good year for innovation in medicine with the FDA approving 45 novel drugs, four more than in 2014 and the most since the all-time record of 53 was set in 1996. Full drug pipelines at many companies suggest the strong rate of new drug approvals is likely to continue with 225 new drug approvals forecast through 2020. But despite the rosy statistics and the prospect for further progress in 2016, the FDA and pharmaceutical industry face challenges.

- Despite criticism drug-makers continue to raise prices (9-10%), citing their struggle to get a decent return on billions spent on R&D and the need to fund risky research. Increased political focus on drug pricing has hit both biotech and specialty company valuations in recent months.
- Related, somewhere deep within the FDA 4,300 generic drug applications await approval. Drug companies are threatening to abandon generics altogether if the FDA doesn't speed things up, while the FDA says sloppy and incomplete applications are slowing the approval process. This backlog of unapproved drugs has been attributed as a reason for high drug prices.
- The FDA and CDC both recently made the news related to their efforts to curb the epidemic of opioid drug abuse. The CDC released new opioid prescription guidelines amid backlash that the guidelines were not clinically astute and were authored by only three individuals. The FDA has unveiled sweeping changes to opioid policies with plans to: reexamine the risk-benefit paradigm; develop a framework for pediatric opioid labeling; change immediate-release opioid labeling; update REMS requirements; and improve access to naloxone, to name a few.

New Drugs: Briviact® (brivaracetam) is an anticonvulsant approved as add-on therapy for partial onset seizures in patients >16 years old, and must be dispensed with a Med Guide. Idelvion® (coagulation factor IX-recombinant, albumin fusion protein), modified to last longer in the blood, is the first coagulation factor-albumin fusion protein product indicated for congenital Factor IX deficiency (hemophilia B) and on-demand control and prevention of bleeding episodes. Ninlaro® (ixazomib), dosed on 3-days of a 28-day cycle, is the first oral proteasome inhibitor and received priority review as an orphan drug to treat multiple myeloma in patients who have received at least one prior therapy. Uptravi® (selexipag) received orphan drug status to treat rare but progressive pulmonary arterial hypertension. Zepatier ™ (elbasvir/grazoprevir), given as a 12-16 week course of treatment, was approved through priority review as a combination drug for chronic hepatitis C. Zurampic® (lesinurad) was approved for use with a xanthine oxidase inhibitor (e.g. allopurinol, febuxostat) to treat hyperuricemia associated with gout; the drug carries a black box warning for renal failure.

New Dosage Forms: Significant new dosage forms that were approved this quarter include: Adzenys XR-ODT™ (amphetamine, orally disintegrating extended-release tablet) for ADHD; Cetylev™ (acetylcysteine, effervescent tablet) for acetaminophen overdose; Odefsey® (emtricitabine/rilpivirine/tenofovir/alafenamide) for HIV-1 infection; Onzetra Xsail™ (sumatriptan, inhalation powder) for migraine headache; Quillichew ER™ (methylphenidate, chewable extended release tablet) for ADHD; Sernivo™ (betamethasone, topical spray) for plaque psoriasis; Vistogard® (uridine, oral granules) for fluorouracil or capecitabine overdose/toxicity; Xeljanz XR® (tofacitinib, extended-release tablet) for rheumatoid arthritis; and Zembrace SymTouch™ (sumatriptan, subcutaneous injection) for migraine. §

Drug Name	Indication	Route	Dosing	Estimated Cost	
Briviact® (brivaracetam)	Partial onset seizures	Oral, IV	Twice-Daily	-	-
Idelvion® (coagulation factor IX, recombinant)	Hemophilia B (Christmas disease)	IV	Variable	$5	IU
Ninlaro® (ixazomib)	Multiple myeloma	Oral	28-Day Cycle	$8,670	Cycle
Uptravi® (selexipag)	Pulmonary arterial hypertension	Oral	Twice-Daily	$17,424	Month
Zepatier™ (elbasvir, grazoprevir)	Chronic hepatitis C	Oral	Once-Daily	$21,840	Month
Zurampic® (lesinurad)	Hyperuricemia-associated gout	Oral	Once-Daily	-	-